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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,629	03/23/2000	RAZI VAGO	229752001000	2656

7590 09/09/2004

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EXAMINER

PHAN, HIEU

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/446,629

Applicant(s)

VAGO, RAZI

Examiner

Hieu Phan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 4-11 is/are rejected.
- 7) ☒ Claim(s) 12,13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 4-7, 11 are rejected under 35 U.S.C. 102(e) as anticipated by White et al. (U.S. Patent 6,376,573) or, in the alternative, under 35 U.S.C. 103(a) as obvious over AIMS (Australian Institute of Marine Science).

White et al. disclose a coralline hydroxyapatite material used as a bone substitute material in oral, periodontal and craniofacial surgery, and orthopedic applications. The coralline material can be obtained from coral such as *Acropora* (column 3 lines 64-67, column 4 lines 1-5, 24-28 and 67 and column 5 lines 1-4). White et al. does not explicitly disclose the use of the coral specie *Acropora grandis* in his patent but it is inherent that the specie was use because White et al. disclose the use of the coral genus *Acropora*, which is the genus of the *Acropora grandis*.

However in the alternative, White et al. does not disclose the coralline material is of the specie *Acropora grandis*.

AIMS disclose one property of *Acropora grandis* is the it's ability to grow rapidly, at an approximate growth rate of 15 cm per year (page 1 lines 28-33). The advantage of

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using the specie *Acropora grandis* is due to the specie *grandis*' ability to grow rapidly, there is a large amount of material to be use as a bone substitute.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teaching of AMS to modify the apparatus White et al. to be made of *Acropora grandis*. The motivation for incorporating the feature of AMS into the apparatus of White et al. is due to the specie *grandis*' ability to grow rapidly, there is a large amount of material to be use as a bone substitute.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. (U.S. Patent 6,376,573) and AIMS (Australian Institute of Marine Science) in view of Laurencin et al. (U.S. Patent 5,766,618).

White et al. and AIMS are explained as before. White et al. and AIMS further lacking the shaped product containing an antibiotic or a growth factor.

Laurencin et al. discloses a hydroxyapatite bone composite having an antibiotic or a growth factor (column 11 lines 40-48). The advantage of having an antibiotic or growth factor incorporated in the hydroxyapatite are the antibiotic would prevent infection and the growth factor would encourage desire cells to grow, which help to promote the healing and integration of the hydroxyapatite material.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teaching of Laurencin et al. to modify the apparatus White et al. and AIMS to have at least one layer is made of a bioabsorbable polymer, at least one layer is made of inorganic fibers and at least one layer includes at least bioactive additive. The motivations for incorporating the feature of Laurencin et al. into the apparatus of White et al. and AIMS are the antibiotic would prevent infection and the growth factor would encourage desire cells to grow, which help to promote the healing and integration of the hydroxyapatite material.

Allowable Subject Matter

5. Claims 12 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

1. Applicant's arguments filed 04/29/2004 have been fully considered but they are not persuasive. In regard to Applicant argument that White et al. does not read on claims 4-11, Examiner disagrees. The newly added limitation," shaped into a form to be implanted or inserted into a human or non-human animal body for medical or related purposes and is formed from a coral" does not exclusively limits the product to be made entirely of unaltered coral. Therefore the rejection under 35 U.S.C. 102(e) as anticipated by White et al. (U.S. Patent 6,376,573) or, in the alternative, under 35 U.S.C. 103(a) as obvious over AIMS (Australian Institute of Marine Science) and the rejection under 35

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U.S.C. 103(a) as being unpatentable over White et al. (U.S. Patent 6,376,573) and AIMS (Australian Institute of Marine Science) in view of Laurencin et al. (U.S. Patent 5,766,618) are proper.


Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hieu Phan whose telephone number is 703-308-8969. The examiner can normally be reached on Monday-Friday from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

Hieu Phan
Examiner
Art Unit 3738



David J. Isabella
Primary Examiner